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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,075	06/25/2004	Mari Tabuchi	1422-0634PUS1	5317

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EXAMINER	
BALL, JOHN C	

ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
09/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,075	TABUCHI ET AL.	
	Examiner	Art Unit	
	J. CHRISTOPHER BALL	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This Office Action based on the Amendment and Remarks filed with the Office on July 17, 2008, regarding the TABUCHI et al. application filed with the Office on June 25, 2004.

2. Claims 1 and 3-8 are currently pending and have been fully considered.

Claim Objections

3. Claim 6 is objected to because of the following informalities: the claim recites in part, ". . . protein dissolved in a liquid component consisting essentially water. . ." This is grammatically incorrect and seems to be missing the article "of". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article by GORDON et al. ("Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72) in view of HAUPT et al. (US 3,901,870).

Regarding claims 1 and 6-8, GORDON teaches preparation of a sample comprising proteins of interest in water (second sentence, first paragraph of "CZE Run Conditions", pg 70) and in a control experiment, protein in only water (fifth paragraph of Results & Discussion, p. 72), for electrophoretic protein separations (remainder of the first paragraph of "CZE Run Conditions", pg 70). Even though the protein in only water is not the preferred method of GORDON, the art does teach the limitation. The proteins separated from the mixture in GORDON (second paragraph of "CZE Run Conditions", pg 70) were not heat denatured in the stated protocol.

GORDON does not teach that the electrophoresis buffer has a pH of 2.0 to 9.0.

However, HAUPT discloses a method of processing a particular protein, wherein is taught use of an electrophoresis buffer with a pH from 8 to 9 (Col. 2, lines 55-61)

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to use an electrophoresis buffer from pH 8 to 9 as taught by HAUPT with the method as taught by GORDON because it would make the method amenable to use in production of alpha-fetoprotein, a diagnostic reagent (HAUPT, Col. 1, lines 31-35).

Regarding claim 5, GORDON teaches the use of capillary zone electrophoresis as the method of electrophoresis.

7. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over GORDON et al. ("Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72) in view of HAUPT et al. (US 3,901,870) as applied to claims 1 and 5-8 above, and further in view of TADAYONI-REBEK et al. (U.S. Patent Application Publication 2002/0155455 A1).

Regarding claims 3 and 4, the combination of GORDON and HAUPT discloses the limitations recited in claim 1 as outlined above.

GORDON and HAUPT do not disclose molecular weight markers subject to electrophoresis together with a protein.

However, TADAYONI-REBEK discloses high homogeneous molecular markers for electrophoresis, wherein is taught the use of marker molecules comprising a collection of two or more marker molecules (paragraph [0019]). TADAYONI-REBEK also teaches the addition of the marker molecule composition to a sample containing protein (paragraph [0022]), which would constitute the following a general protocol for an electrophoresis method.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the protocol of GORDON and HAUPT with the utilization of molecular weight markers taught by TADAYONI-REBEK because doing so allows one to obtain highly homogeneous visible molecular markers that are compatible with commercially available separation techniques (TADAYONI-REBEK et al., last sentence of paragraph [0011]).

Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to try various concentrations of the molecular weight markers in the electrophoresis process. This would include adjusting the concentration of a molecular weight marker below a comparable standard concentration, as recited in claim 3; or adjusting the concentration of a molecular weight marker to some level between 0.1 and 10 times the concentration of the protein being tested, as recited in claim 4. Adjusting the concentration level of reagents, including molecular weight markers, would be obvious for one of

ordinary skill in the art to attempt in an effort to optimize the electrophoresis separation. See MPEP 2144.05 (II).

Response to Arguments

8. Applicant's arguments, see page 6, filed July 15, 2008, with respect to the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

9. Applicant's arguments, see page 6, filed July 15, 2008, with respect to claims 1-4 have been fully considered and are persuasive. The objection of claims 1-4 has been withdrawn.

10. Applicant's arguments, see page 7, filed July 15, 2008, with respect to claim 3 (mistakenly listed as claim 4 in the previous Office Action of February 2008) have been fully considered and are persuasive. The 35 USC 112, Second Paragraph rejection of claim 3 has been withdrawn.

11. Applicant's arguments, see page 7+, filed July 15, 2008, with respect to the rejection(s) of claim(s) 1-5 under 35 USC 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the teachings of HAUPT et al.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL, Ph.D. whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JCB
AU 1795
09/09/2008